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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/083,815 | 02/27/2002 | Christen Marie Anderson | 660088.435C2 | 8204 |

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SEED INTELLECTUAL PROPERTY LAW GROUP PLLC
701 FIFTH AVE
SUITE 6300
SEATTLE, WA 98104-7092

EXAMINER

RAO, MANJUNATH N

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1652

DATE MAILED: 04/22/2003

(Handwritten mark)

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/083,815

Applicant(s)

ANDERSON ET AL.

Examiner

Manjunath N. Rao, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-85 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-85 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-7, drawn to a method of identifying an agent that alters mitochondrial ATP production by comparing the level of binding of ATP synthase inhibitor to an ATP synthase in the presence and absence of a candidate compound, classified in class 435, subclass 4.
- II. Claims 8-12, drawn to a method of identifying an agent that alters mitochondrial ATP production by monitoring the levels of ATP production, classified in class 435, subclass 4.
- III. Claims 13-19, drawn to a method of treating diabetes comprising administering to a patient in need thereof an effective amount of a compound (structure unknown) that increases the synthesis of mitochondrial ATP in cells, decreases the hydrolysis of mitochondrial ATP in cells or does both, classified in class 514, subclass 789.
- IV. Claims 20-21, drawn to a method for identifying an agent useful for treating diabetes by comparing level of ATP in treated and untreated samples, classified in class 435, subclass 4.
- V. Claims 22-37, drawn to a method for identifying an agent that alters glucose homeostasis, classified in class 435, subclass 4.
- VI. Claims 38-44, drawn to a method for identifying an agent that alters mitochondrial ATP hydrolase activity, classified in class 435, subclass 18.

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- VII. Claims 45-51, drawn to a method for identifying an agent for treating diabetes by measuring the ATP hydrolase activity, classified in class 435, subclass 18.
- VIII. Claim 52, drawn to an agent of unknown chemical nature, classified in class 514, subclass 789.
- IX. Claim 53-57, drawn to a fusion protein comprising an optional epitope tag fused to IF1, classified in class 530, subclass 350.
- X. Claims 58-68, 76 drawn to a fusion protein comprising an optional epitope tag, fused to a cellular transport sequence which is fused to an organellar targeting sequence which is fused to IF1, classified in class 530, subclass 350.
- XI. Claims 69-75, drawn to a fusion protein comprising an optional epitope tag fused to a cellular transport sequence fused to an IF1 polypeptide, classified in class 530, subclass 350.
- XII. Claims 77-82, drawn to a fusion protein comprising an optional epitope tag fused to a cellular transport sequence, classified in class 530, subclass 350.
- XIII. Claims 83-85, drawn to nucleic acids and host cells and a method of making a fusion protein, classified in class 435, subclass 69.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I through VII are patentably distinct from each other. The method of identifying an agent that alters mitochondrial ATP production by comparing the level of binding of ATP synthase inhibitor to an ATP synthase in the presence and absence of a candidate compound of group I, the method of identifying an agent that alters mitochondrial ATP production by monitoring the levels of ATP production of group II, the method of treating

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diabetes comprising administering to a patient in need thereof an effective amount of a compound (structure unknown) that increases the synthesis of mitochondrial ATP in cells, decreases the hydrolysis of mitochondrial ATP in cells or does both in group III, the method for identifying an agent useful for treating diabetes by comparing level of ATP in treated and untreated samples of group IV, the method for identifying an agent that alters glucose homeostasis of group V, the method for identifying an agent that alters mitochondrial ATP hydrolase activity of group VI, the method of identifying an agent for treating diabetes by measuring the ATP hydrolysis activity of group VII are all unrelated as they comprise distinct steps, utilize different products and produce different results. The groups have acquired separate status in the art and separate fields of search as further evidenced by their separate classification.

Inventions VIII through XIII are patentably distinct from each other. The chemical agent of group VIII, the polypeptides of groups IX through XII, the polynucleotide of group XIII, each comprise a chemical compound of unknown structure, amino acid sequences and nucleotide sequences which are chemically unrelated, do not require each other for practice; have separate utilities, such as use of the group VIII chemical compound to treat diabetes, versus the use of fusion proteins to assay binding activity or enzyme activity, versus the use of polynucleotide in a hybridization reaction and are subject to separate manufacture and sale. The groups have acquired separate status in the art and separate fields of search.

Inventions VIII through XII and inventions I through VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can

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be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the fusion proteins of groups VIII through XII can be used to raise specific antibodies as opposed to its use in the methods of groups I through VII.

Inventions XIII and inventions I through VII are patentably distinct from each other. The product of group XIII, i.e., the nucleic acid molecule is neither used nor made in the methods of groups I through VII. They are subject to separate manufacture and sale. The groups have acquired separate status in the art and separate fields of search.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Species Election

This application contains claims directed to the following patentably distinct species of the claimed invention:

Methods using 1) mouse IF1,

2) rabbit IF1,

3) bovine IF1,

4) canine IF1,

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- 5)non-human primate IF1,
- 6)a human IF1,
- 7)IF1 fragment 14-47 as set forth in SEQ ID NO:29,
- 8)IF1 fragment 14-46 as set forth in SEQ ID NO:67,
- 9) IF1 fragment 14-45 as set forth in SEQ ID NO:66,
- 10) IF1 fragment 14-44 as set forth in SEQ ID NO:65,
- 11) IF1 fragment 14-43 as set forth in SEQ ID NO:64,
- 12) IF1 fragment 14-42 as set forth in SEQ ID NO:63,
- 13) IF1 polypeptide with SEQ ID NO:12,
- 14) IF1 polypeptide with SEQ ID NO:13,
- 15) IF1 polypeptide with SEQ ID NO:29,
- 16) IF1 polypeptide with SEQ ID NO:63,
- 17) IF1 polypeptide with SEQ ID NO:64,
- 18) IF1 polypeptide with SEQ ID NO:65,
- 19) IF1 polypeptide with SEQ ID NO:66,
- 20) IF1 polypeptide with SEQ ID NO:67,
- 21) Epitope tag sequence SEQ ID NO:1,
- 22) Epitope tag sequence SEQ ID NO:2,
- 23) Epitope tag sequence SEQ ID NO:3,
- 24) Epitope tag sequence SEQ ID NO:4,
- 25) Epitope tag sequence SEQ ID NO:5,
- 26) Epitope tag sequence SEQ ID NO:6,

- 27) Epitope tag sequence SEQ ID NO:7,
- 28) Epitope tag sequence SEQ ID NO:8,
- 29) Epitope tag sequence SEQ ID NO:9,
- 30) Epitope tag sequence SEQ ID NO:68,
- 31) Tat sequence with SEQ ID NO:10,
- 32) Tat sequence with SEQ ID NO:27,
- 33) Tat sequence with SEQ ID NO:70,

Applicant is required under 35 U.S.C. 121 to elect a single disclosed **(i.e., a single IF1 species or a single epitope tag sequence or a single Tat sequence from the above list as it applies to the elected group)** species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims in each specific group are generic to that specific group.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

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Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

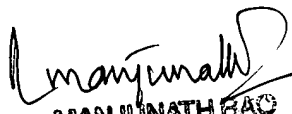
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manjunath N. Rao, Ph.D. whose telephone number is 703-306-5681. The examiner can normally be reached on 7.30 a.m. to 4.00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 703-308-3804. The fax phone

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numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-306-0196.



MANJUNATH RAO
PATENT EXAMINER

Manjunath N. Rao
April 18, 2003